

REMARKS

Applicants thank the Examiner, Supervisory Patent Examiner Smith and Quality Assurance Specialist Woodward for the courtesy of their time and comments during the interview with applicants' representative on April 11, 2005.

Prior to examination of this application, applicants respectfully request a personal interview with the Examiner and include herewith an Applicant Initiated Interview Request form (PTOL – 413A). Applicants request that the examiner contact the undersigned to arrange a mutually convenient date and time to conduct the interview prior to examination of this RCE application.

Applicants have carefully considered the Final Office Action mailed September 2, 2004, as well as the Advisory Actions mailed February 16, 2004 and April 7, 2004 and submit herewith the instant Amendment and Request for Continued Examination. Entry of the amendment, as well as reconsideration and withdrawal of the outstanding rejections, is respectfully requested. Applicants assert that the amendment presented herein does not constitute new matter and places the application in condition for allowance. Early notice to that effect is urgently requested.

Support for the amendments to the claims may be found throughout the specification and claims as originally filed. For example, support for multifocal injections may be found on page 5, line 9; and support for administration to an afflicted area of the face may be found on page 5, lines 15-16; and page 7, lines 18-19. Support for excluding the brow and upper or lower eyelid may be found, for example, in the sentence spanning pages 4-5.

Status of the Claims

Upon entry of the foregoing amendment, claims 16-19 will be pending.

Information Disclosure Statement

Applicants acknowledge, with appreciation, receipt of a signed, dated and fully initialed copy of the form PTO 1449 filed with the Amendment and Response dated May 25, 2004.

Election/Restriction

Applicants acknowledge, with appreciation, withdrawal of the previous requirement for election of species between trigeminal neuralgia and facial pain. Applicants note that the two will be examined as one species.

Claim Objections

Applicants acknowledge, with appreciation, the withdrawal of the claim objection.

The Rejection of Claims 16-19 under 35 U.S.C. § 102(e)

Claims 16-19 stand rejected under 35 U.S.C. § 102(e) for allegedly being anticipated by U.S. Pat. No. 6,464,986 to Aoki *et al.* (the '986 patent). Applicants respectfully traverse the rejection for the following reasons.

The Final Office Action mailed September 2, 2004 maintains the rejection originally set forth in the Office Action mailed November 26, 2003 because it is alleged that the '986 patent

teaches treatment of neuropathic pain syndromes, including trigeminal neuralgia. Applicants respectfully disagree.

The claims, as presently amended, are directed to a method of treating facial pain caused by trigeminal neuralgia comprising administering to a patient in need thereof multifocal injections of a therapeutically effective amount of botulinum toxin to an afflicted area of the face, excluding the brow and upper or lower eyelid, of said patient, thereby reducing or eliminating said facial pain caused by trigeminal neuralgia.

Nothing in the '986 patent teaches or suggests the claimed invention. In fact, the '986 patent teaches away from what applicants have invented and it does not enable such methods. Additionally, limitations recited in the claims are not taught or suggested in the '986 patent and the Office Action does not indicate where these limitations appear in the reference.

The claims, as presently amended, require multifocal injections of an effective amount of botulinum toxin to an afflicted area of the face of a patient. This is simply not taught or suggested in the '986 patent. At column 15, lines 55-58 of the '986 patent, administration of botulinum toxin to the head and neck of a patient is expressly excluded. This express exclusion of the head and neck teaches away from the present invention because the claims specifically require administration of botulinum toxin via multifocal injections to an afflicted area of the face of a patient. The face is part of the head and neck. Accordingly, nothing in the '986 patent teaches or even remotely suggests a method of treating facial pain caused by trigeminal neuralgia and nothing in the '986 patent teaches or suggests a method of treating this affliction by multifocal injections of botulinum toxin to an afflicted area of the face of a patient.

The rejection is also improper because express limitations required in the claims are absent from the '986 patent and are nowhere addressed in the Office Action. For example, multifocal injections in the face, excluding the brow and upper or lower eyelid (claim 16) are not taught or suggested in the '986 patent. Trigeminal neuralgia associated with trauma (claim 17) is not taught or suggested in the '986 patent. Methods of treating facial pain caused by trigeminal neuralgia using the recited dosages (claim 18) are not taught or suggested in the '986 patent. Methods of treating facial pain caused by trigeminal neuralgia wherein the botulinum toxin is selected from the group consisting of immunotypes A-G (claim 19) is not taught or suggested in the '986 patent.

Additionally, the '986 patent does not enable a method of treating facial pain caused by trigeminal neuralgia. A person having skill in the art, reading the '986 patent, would be led away from what is currently claimed because limitations expressly required by the claims are not taught and the required site of administration for treating facial pain caused by trigeminal neuralgia is expressly excluded from the patent. The only reference to treating facial pain appearing in the '986 patent occurs in Example 4. This example, however, is directed to treating nasopharyngeal tumor pain using a bolus injection. This is not the same as what is being claimed. Nasopharyngeal tumor pain is not facial pain caused by trigeminal neuralgia. And bolus injection is not multifocal injection. Applicants reiterate that nothing in the '986 patent teaches or suggests the claimed method of treating facial pain caused by trigeminal neuralgia.

It is axiomatic that a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently, in a single prior art reference. Should the

examiner maintain the rejection, applicants respectfully request that a clear indication be made of where each and every element in all of the pending claims, including the dependent claims, is taught in the reference.

Applicants respectfully assert that, not only does the '986 patent teach away from what is currently claimed, but it also does not enable an invention directed to treating facial pain caused by trigeminal neuralgia by administering multifocal injections to an afflicted area of the face, excluding the brow and upper or lower eyelid, of a patient. Express limitations required by the claims are not taught in the reference and the Office Action does not indicate where they are taught. Applicants assert that the rejection is improperly maintained and request that it be reconsidered and withdrawn.

The Rejection of Claims 16-19 under 35 U.S.C. § 102(b)

Claims 16-19 stand rejected under 35 U.S.C. § 102(b) for allegedly being anticipated by U.S. Pat. No. 5,714,468 to Binder (the '468 patent). Applicants note that the final office action and advisory actions cite 35 USC § 102(e) in connection with the '468 patent. Clarification is requested. Applicants respectfully traverse the rejection for the following reasons.

The Final Office Action mailed September 2, 2004 maintains the rejection originally set forth in the Office Action mailed November 26, 2003 because it is alleged that the '468 patent teaches treatment of facial pain caused by trigeminal neuralgia. Applicants disagree.

Headache pain is not the same as facial pain caused by trigeminal neuralgia. The '468 patent is directed to treating headache pain, not facial pain caused by trigeminal neuralgia.

Nothing in the ‘468 patent teaches the claimed methods because the pain described in the ‘468 patent is not facial pain caused by trigeminal neuralgia. Rather, the pain discussed in the ‘468 patent is headache pain. As applicants have set forth previously, and the Final Office Action acknowledges, the art recognizes that headache pain and trigeminal neuralgia are distinct.

To overcome this acknowledged distinction, the Final Office Action alleges that the ‘468 patent teaches that “botulinum toxin can be used to treat any of these disorders” and cites column 6, lines 58-67 and column 7, lines 1-3 in support of this proposition. The cited passage is reproduced below:

For example, as shown in the data presented in the Examples, the method of the invention was effective in reducing headache pain even in persons who only received an extramuscular injection of presynaptic neurotoxin. Moreover, reduction of headache pain was unexpectedly observed even in patients whose pain was causally related to vascular or neurological components; e.g., classical migraine, trigeminal neuralgia and trauma headache. However, those of ordinary skill in the art will recognize that additional therapeutic benefits may be achieved through introduction of the presynaptic neurotoxins of the invention into musculature (particularly in the back) where muscle spasm or strain is present. [‘468 patent at col. 6, lines 58-67 and col. 7, lines 1-3, emphasis added.]

Applicants emphatically assert that nothing in this passage (or anything else in the patent) teaches or suggests the claimed methods. Moreover, the assertion made in the Office Action that “botulinum toxin can be used to treat any of these disorders” is not an accurate characterization of the ‘468 patent. There is simply no teaching or suggestion anywhere in any of the references of record that facial pain caused by trigeminal neuralgia can, or even should, be treated using botulinum toxin. At best, the passage reproduced above indicates that reduction of headache pain was unexpectedly observed even in patients whose pain was causally related to trigeminal

neuralgia. This is just not the same as treating facial pain caused by trigeminal neuralgia. The passage goes on to suggest introduction of presynaptic neurotoxin in musculature (particularly in the back) but this is also not a teaching of the presently claimed methods of treating facial pain caused by trigeminal neuralgia. The back and the face are different parts of a person's body and a suggestion to introduce presynaptic neurotoxin in musculature (particularly in the back) is not a suggestion to treat facial pain caused by trigeminal neuralgia.

Applicants assert that the rejection is improper because, as set forth in the section above, the Office Action does not address express limitations present in the claims. For example, multifocal injections in the face (claim 16) are not taught or suggested in the '468 patent. Trigeminal neuralgia associated with trauma (claim 17) is not taught or suggested in the '468 patent. Methods of treating facial pain caused by trigeminal neuralgia using the recited dosages (claim 18) are not taught or suggested in the '468 patent. Methods of treating facial pain caused by trigeminal neuralgia wherein the botulinum toxin is selected from the group consisting of immunotypes A-G (claim 19) is not taught or suggested in the '468 patent.

Reconsideration and withdrawal of the rejection is requested.

Conclusion

Applicants respectfully request reconsideration and withdrawal of the outstanding rejections and early allowance of the pending claims. Should the Examiner find that a telephone interview would further prosecution of the application, she is invited to contact the undersigned at her convenience.

U.S. Application Serial No. 10/040,830
Attorney Docket No.: 33677-00700

The Commissioner is authorized to charge any additional fees associated with this filing, or credit any overpayment, to Deposit Account No. 13-3250. **EXCEPT** for issue fees payable under 37 C.F.R. § 1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. §§ 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account 13-3250. This paragraph is intended to be an **CONSTRUCTIVE PETITION FOR EXTENSION OF TIME** in accordance with C.F.R. § 1.136(a)(3).

Respectfully submitted,

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